9-6-88

Accession Number 406386-23

DATA EVALUATION RECORD

1. **CHEMICAL:** MON 7200/MON 15100

2. **TEST MATERIAL:** MON 7200, 91.5% purity, an orange solid.

3. **STUDY TYPE:** Freshwater Fish Acute Static Test.
   Species Tested: Salmo gairdneri.

4. **CITATION:** Bowman, J. H. 1987. Acute Toxicity of MON 7200 to Rainbow Trout (Salmo gairdneri). Prepared by Analytical Bio-Chemistry Laboratories, Inc., Columbia, Missouri. Submitted by Monsanto Agricultural Company, St. Louis, Missouri. Study Number 36025/AB-87-90. Accession Number 406386-23.

5. **REVIEWED BY:**

   Prapimpan Kosalwat, Ph.D.
   Staff Toxicologist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: P. Kosalwat
   Date: 7/25/88

6. **APPROVED BY:**

   Isabel C. Johnson, M.S.
   Principal Scientist
   KBN Engineering and
   Applied Sciences, Inc.

   Signature: Isabel C. Johnson
   Date: 7-26-88

   for Henry T. Craven
   Supervisor, EEB/HED
   USEPA

   Signature: Richard M. Lee
   Date: 8/16/'88

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a freshwater fish acute test. With an LC50 value of 0.46 mg a.i./L mean measured concentration, MON 7200 is considered highly toxic to Salmo gairdneri. The NOEC was determined to be 0.19 mg a.i./L mean measured concentration.

8. **RECOMMENDATIONS:** N/A.

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9. BACKGROUND: MON-15100 and MON-7200 are Monsanto designations for the same active ingredient. MON-15151 is the designation for the 1 pound a.i. per gallon emulsifiable concentrate (1EC) formulation.

10. DISCUSSION OF INDIVIDUAL TESTS: N/A.

11. MATERIALS AND METHODS:

A. Test Animals: The rainbow trout (Salmo gairdneri) used in the test were obtained from Mt. Lassen Trout Farm in Red Bluff, CA. All test fish were held in culture tanks on a 16-hour daylight photoperiod and observed for at least 14 days prior to testing. During this period, the fish received a standard commercial fish food occasionally supplemented with brine shrimp nauplii (Artemia sp.) daily until 48-96 hours prior to testing at which time feeding was discontinued. The rainbow trout used in this experiment had a mean weight of 0.58 (± 0.11) g and a mean standard length of 33 (± 2.1) mm.

B. Test System: The static fish bioassay was conducted in five-gallon glass vessels containing 15 liters of soft reconstituted water. The water had an initial pH of 7.2-7.6; and a total hardness and a total alkalinity of 40-48 and 25-35 mg/L as $CaCO_3$, respectively. The 0-hour measured control water parameters of this dilution water were dissolved oxygen 9.7 mg/L and pH 7.5. The test vessels were kept in a water bath at 12 ± 1.0°C. The test fish were acclimated to the dilution water prior to testing.

C. Dosage: 96-hour acute static LC50 test.

D. Design: Based on the results of preliminary testing and a previous definitive test, five nominal concentrations of the test compound (0.10, 0.18, 0.32, 0.56, and 1.0 mg/L), with ten fish per concentration, were selected for the definitive bioassay. Also included were a dilution water control and a solvent control chamber. All test concentrations were corrected for sample purity. The solvent control chamber received a 0.5 ml aliquot of dimethylformamide (DMF), which was equivalent to the highest amount used in any test solution.

The fish were added to the test chambers by random assignment within 30 minutes after addition of test material. The loading biomass of fish per test chamber was 0.39 g/L. All test organisms were observed once

every 24 hours for mortality and abnormal (sub-lethal) effects. Any dead individuals were removed from the test chambers after each 24-hour observation.

E. Statistics: Statistical analyses were obtained using Stephan's computer program.

12. REPORTED RESULTS: Table 3 (attached) presents mortality rates and water quality measurements during the exposure period. Water temperature, dissolved oxygen concentration, and pH were within acceptable limits throughout the study. The 24-, 48-, and 96-hour LC50 values for MON 7200 were >1.0, 0.66, and 0.48 mg/L nominal concentrations, respectively. The 96-hour no-observed-effect concentration (NOEC) was estimated to be 0.18 mg/L based on the lack of mortality or observed abnormal (sub-lethal) effects. The abnormal effects of mortality, surfacing and/or excitability were observed in the 0.32-, 0.56-, and 1.0-mg/L test concentrations during the exposure period.

At 0 hour, all test solutions had particles of precipitate on the surface of the solutions and the amount increased with the concentration. Also present at 0 hour was a light surface film in the 1.0-mg/L chamber. After 24 hours, the 1.0-mg/L solution had a few particles of precipitate on the surface which disappeared at 96 hours. Other test solutions with lower concentrations of MON 7200 had no visible precipitate or surface film after 24 hours.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES: No conclusion was made by the author. The study was conducted following the intent of the Good Laboratory Practice Regulations and the final report was reviewed and signed by Analytical Bio-Chemistry Laboratories' Quality Assurance Unit.

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:

A. Test Procedure: The test procedure was generally in accordance with the SEP guidelines, except for the following deviations:

o The age of test fish was not reported.

o Each nominal test concentration was less than 60% (approximately 56%) of the next highest concentration.

o There was no 15- to 30-minute transition period between light and dark photoperiod.

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o The test temperature was measured every 48 hours. If temperature is controlled by a water bath, the SEP recommends that measurements be recorded every six hours.

o In Table 1 of Appendix II (attached), the analysis of MON 7200 showed the unit of test levels as mg/mL, which contradicts the unit of mg/L used throughout the report. The reviewer checked the stock solution preparation record on page 28 and it confirmed that the concentrations were in mg/L unit.

B. Statistical Analysis: Since chemical analysis of the test solutions was conducted at the beginning and end of the test, the estimation of LC50 value using mean measured concentrations would have reflected a more accurate toxicity result. The reviewer recalculated the 96-hour LC50 value with mean measured concentrations in Table 1, Appendix II (attached), using EPA's TOXANAL computer program (attached) and reported it as a result of this study.

C. Discussion/Results: A 96-hour LC50 value of 0.46 mg a.i./L mean measured concentration (95% confidence limits = 0.36-0.61 mg/L) classifies MON 7200 as highly toxic to rainbow trout. The NOEC was determined to be 0.19 mg a.i./L mean measured concentration.

D. Adequacy of the Study:

(1) Classification: Core.

(2) Rationale: Although the test procedure deviated from the recommended protocol, the reviewer does not believe that it significantly affected the toxicity results.

(3) Repairability: N/A.

15. COMPLETION OF ONE-LINER: Yes, July 18, 1988.

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 CHLORAT  MOUTON  SALMO GAIRDNERI  7-14-88
 ********************************************************************************
 CONC.     NUMBER        NUMBER        PERCENT       BINOMIAL
           EXPOSED       DEAD          DEAD          PROB.(PERCENT)
  1.1      20            20            100           9.765625E-02
  .89      20            5             50            20.69467
  .57      20            2             10            3.46875
  .19      20            0             0             9.765625E-02
  1.4000001E-02          20            1             (
9.765625E-02

 THE BINOMIAL TEST SHOWS THAT .19 AND 1.1 CAN BE
 USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
 CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
 ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.


 AN ARBITRARY .19 FOR THE SET OF DATA IS .89


 PROBITS CALCULATED USING THE MOVING AVERAGE METHOD
 SLOPE          N          LOG              95 PERCENT CONFIDENCE LIMITS
  3          .18177      .48724PB      .0870295      .8181827


 PROBITS CALCULATED USING THE PROBIT METHOD
 NUMBER GROUPS        G         H    GOODNESS OF FIT PROBABILITY
      5         .11.7972      3           .41.0275

 SLOPE   =              4.8111149
 95 PER CENT CONFIDENCE LIMITS = 1.1.0.0.1.1    AND    7.0410107

 LOG =    .4871144
 95 PERCENT CONFIDENCE LIMITS =  .0691481 AND  .8548981

 LOG =    .2661145
 95 PERCENT CONFIDENCE LIMITS =  .1464893 AND  .3547736
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Chemical Name MON 7200 Chemical Class ____ Page 1 of ____

No. ____

Study/Species/Lab/ Succession	Chemical % a.i.	Results	Reviewer/ Date	Validat: Status
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg (95% C.L) Contr. Mort.(%)=		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
14-Day Single Dose Oral LD_{50}		LD50 = mg/kg. (95% C.L) Contr. Mort.(%)=		
Species ____		Slope= # Animals/Level= Age(Days)= Sex =		
Lab		14-Day Dose Level mg/kg/(% Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L.) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = ppm (95% C.L) Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Age(Days)= Sex =		
Lab ____		8-Day Dose Level ppm/(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		
8-Day Dietary LC_{50}		LC50 = pp__ (95% C.L.) Contr. Mort.(%)= Sol. Contr. Mort.(%)=		
Species		Slope= # Animals/Level= Temperature =		
Lab ____		96-Hour Dose Level ppm /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc		Comments:		
96-Hour LC_{50}		LC50 = 0.46 * ppm (95% C.L. (0.36 - 0.61)) Con. Mor(%)= 0 Sol. Con. Mor.(%)= 0	DK/7-18-88	Cor
Species Salmo gairdneri 91.5		Slope= N/A # Animals/Level= 10 Temp.= 12°C		
Lab Analytical Bio-Chemistry Laboratories, Inc.		96-Hour Dose Level * ppm/(%Mortality) 0.091(0), 0.191(0), 0.27(20), 0.59(50), 1.01(100)		
Acc. 406386-23		Comments: * mean measured concentration (a.i.)		
96-Hour LC_{50}		LC50 = pp__ (95% C.I.) Con. Mort.(%)= Sol. Con. Mort.(%)=		
Species		Slope= # Animals/Level= Temp.=		
Lab ____		96-Hour Dose Level ppm /(%Mortality) ( ), ( ), ( ), ( ), ( )		
Acc.		Comments:		

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